



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/047,789	1-17-96	BARTLEY	A2900

AMGEN INC.
US PATENT OPERATIONS, INC.
4701 TOWER PARK DR.
1540 DEERFIELD RD.
THOUSON, MD 20883-7230

187-2, COM14

ART-UNIT	PAPER NUMBER
19	19

DATE MAILED:

2/14/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 11/29/96 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, FTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 78-89 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 1-77 have been cancelled.

3. Claims _____ are allowed.

4. Claims 78-89 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

347780.2
2/7/97

EXAMINER'S ACTION

Part III: Detailed Office Action

Newly submitted claims 78-89 are pending and under consideration.

Formal Matters:

5 The rejection of claims 75-77 under 35 U.S.C. §112, first paragraph is withdrawn in view of applicants' arguments and/or amendments.

Applicants have submitted an extensive, 14 page PTO-1449 with their response. In the previous Office Action, applicants were invited to submit copies of reference which had properly been cited, but of which copies were unavailable. Of the references on the instant PTO-1449, only citations B1, B4, B6, B8-B10, B13, B21, C13, C23, C27, C28, C30, C32, C34-C37, C42, C44, C45, C48, C49, C53, C55, C58, C72, C76, C84, C85, C87, C101, C114, C117, C120, C131, C136, C143, C146, C151, C152, C153, C156-C160, C165, C177, C185, C196, C236 and C237 meet this criterion. Of those, copies of reference C32 (Francis et al.) and C177 (Fisher et al.) were not submitted, therefore these references have not been considered. The remainder of the listed references have either already been made of record, or alternatively are not in compliance with the provisions of MPEP 609, and have therefore not been considered.

20 The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

✓ The oath or declaration is defective because:

25 It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. § 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Applicants intention to file a substitute declaration is noted; however, no such paper

accompanied the amendment filed 11/29/96.

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/29/96 have been approved.

5

The amendment filed 11/29/96 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in adding the appropriate cross reference to related applications to the specification as required by the Examiner, applicants additionally included a phrase incorporating by reference those related applications. Insofar as any material may exist in those related applications which did not appear in the instant specification as filed, such incorporation by reference after the filing date of the instant application constitutes new matter. Applicants are reminded that a claim to priority to an earlier filed application is not synonymous with incorporation by reference of all material disclosed therein.

15
✓ Applicant is required to cancel the new matter in the response to this Office action.

20
✓ The specification remains objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l). Correction of the following is required: There is no basis in the specification for the limitation of a nucleic acid encoding a polypeptide having as its C-terminus an amino acid from positions 172-265 of Figure 11. Although such would be enabled by the specification, there is no indication in the specification that this particular range was envisioned.

25
✓ Applicants traversal of this objection is noted, but is not deemed persuasive. Applicants have erroneously interpreted this objection as a rejection under 35 U.S.C. §112, first paragraph, which it is not. This is merely an objection that the specification does not support the limitation. As the limitation was found in originally filed claims, applicants may properly correct the problem by amending the specification to recite the particular limitation, so long as it is recited

in a manner equivalent to as disclosed in the original claims, without having such an amendment considered to be new matter.

Double Patenting Rejections:

5 The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

10 A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

15 Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20 Claims 78-89 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-44 of copending application Serial No. 08/252628. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to fragments of the nucleic acids of the copending claims, which fragments are not patentably distinct from the nucleic acid encoding the protein in its entirety.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants arguments filed 11/29/96 have been fully considered but are not deemed persuasive. Applicants argument of *Genentech v. Wellcome* is noted. However, the issues involved in an infringement trial are not the same as those involved in determining patentable distinctness of two inventions. In the instant case, the Examiner maintains the position that the truncated DNAs are obvious over the full length, as it would have been obvious to the person of ordinary skill in the art, having the full length, to use subsets of such for example as hybridization probes, etc. Thus, the claimed compositions themselves are obvious. With regard to applicants argument that it would not have been predictable that such truncations would retain the ability to encode a protein with biological activity, it is noted that such a property is merely an inherent property of the obvious nucleic acids. It has long been established that mere recitation of a newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art (*In re Swinehart and Sflogoj*, 169 USPQ 226).

Request
on request
for consideration

Applicants further arguments that the Patent Office has issued numerous patents to truncated *proteins* based on previously known *proteins* is not persuasive, as the issue here is the obviousness of the nucleic acids which encode the proteins, which are considered obvious for reasons cited immediately above. Further, each case must be examined on its individual merits; the fact that truncations of one molecule have been found to be allowable does not impart allowability to all possible similar claims in unrelated cases.

The Examiner notes that no provisional double patenting rejections over the claims of Application Serial No. 08/321488 are applicable.

25

Advisory Information:

Applicant's amendment necessitated the new grounds of objection/rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the

Serial Number 08/347780
Art Unit 1812

extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE 5 EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) 10 WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

15 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Stephen Walsh, can be reached at (703)308-2957.
20

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile 25 transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The Art Unit 1812 Fax Center number is (703) 308-0294. NOTE: If 30 Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the Examiner at the telephone number above when a fax is being transmitted.

35


LMS
347780.2
2/7/97


STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800